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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,994	04/19/2004	Cynthia T. Clague	P-21018.00	3521
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MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MINNEAPOLIS, MN 55432-9924			EXAMINER WALLENHORST, MAUREEN	
			ART UNIT 1797	PAPER NUMBER
			MAIL DATE 11/02/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/826,994

Applicant(s)

CLAGUE ET AL.

Examiner

Maureen M. Wallenhorst

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 21-43 is/are rejected.
- 7) ☒ Claim(s) 3-20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 8/20/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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1. The disclosure is objected to because of the following informalities: The amendment to paragraph [01] on page 1 of the specification made in the response dated August 6, 2007 is not proper since the petition to make the instant application a continuation-in-part (CIP) of application serial no. 11/047, 026 has been dismissed as inappropriate since 35 USC 120 permits an Applicant to claim the benefit of an **earlier** filing date of a **prior-filed** nonprovisional application. Since the instant application was filed on April 19, 2004, and application serial no. 11/047,026 was filed on January 31, 2005, application serial no. 11/047,026 is a **later-filed** application. Therefore, 35 USC 120 and 37 CFR 1.78 do not apply. Appropriate correction is required.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thornton*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-2, 21-23 and 41-43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 21, 42, 44-46, 71, 78-79 and 85-86 of copending Application No. 10/892,000. Although the conflicting claims are not identical, they are not patentably distinct from each other because each set of claims recites a system, a test cartridge and a method for performing a coagulation time test on a biologic test sample that comprises a test cartridge formed of a cartridge housing having at least one test chamber therein into which a test sample is deposited, an agitator mounted at a pivot point in the test chamber having an agitator vane adapted to be swept about the pivot point through the test sample, a test instrument having a receptacle for supporting the test cartridge therein, a sweeping means in the test instrument for sweeping the agitator vane about the test chamber pivot point through the test sample, detecting means in the test instrument for detecting a reduction of sweeping movement of the agitator vane, and timing means in the test instrument for timing a coagulation test time elapsed from the commencement of sweeping of the agitator vane until detection of the reduction of the sweeping movement.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claim 21 is rejected under 35 U.S.C. 102(e) as being anticipated by Nippoldt et al (US 2005/0255601, submitted in the Information Disclosure Statement filed on February 9, 2006).

Nippoldt et al teach of a blood coagulation test cartridge, system and method. In the embodiment depicted in Figure 6, the test cartridge 50 comprises a cartridge housing 52 having a substantially prismatic shape with first and second major sides 54 and 56, and a minor sidewall 58 extending between the first and second major sides 54, 56. The cartridge housing 52 is formed of a transparent and relatively rigid material. The cartridge contains a blood receptacle or test chamber 82 therein that has a centrally disposed axle or pivot point 84 extending from the closed side 56. An impeller or agitator 90 is supported along the length of the axle 84 for rotation about the axle 84. The impeller 90 can be formed as a propeller, opposed fins, opposed paddles, or opposed blades with perforations therein. See Figure 6 in Nippoldt et al that depicts the agitator 90 as having opposed vane leaflets having curved concave or convex sides, notched sides, slotted sides or as a window having a mesh covering. Movement of the agitator 90 causes a blood sample in the test chamber 82 and reagents therein to be mixed together. The impeller is preferably formed of a metal that is magnetizable or responds to a magnetic field. A motor driven or hand driven magnet can be applied in proximity to the second surface 56 of the cartridge in axial alignment with the axle 84 and rotated. The rotating magnetic field that is produced envelops the agitator 90 and causes it to rotate about the axle 84, whereby the agitator

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90 mixes the blood deposited into the chamber 82. The blood chamber can be coated with a reagent that serves to initiate coagulation in a blood sample such as kaolin, celite, glass particles, thrombin or thromboplastin so that coagulation tests such as thrombin time, PT, aPTT and ACT can be performed. See paragraphs 0041, 0044 and 0047 in Nippoldt et al. It is noted that the "whereby" clause in instant claim 21 has no patentable weight since claim 21 is directed towards an apparatus, and the "whereby" clause in claim 21 is directed to an intended use of the apparatus, which the apparatus disclosed by Nippoldt et al would also be capable of performing since the structure of the device taught by Nippoldt et al is the same as the structure recited in instant claim 21.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 22-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nippoldt et al. For a teaching of Nippoldt et al, see previous paragraphs in this Office action.

Nippoldt et al fail to teach that the test chamber in the cartridge housing is enclosed, and fail to teach of each of the different shapes of the agitator vane leaflets as recited in instant claims 22-40. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to enclose the test chamber in the cartridge taught by Nippoldt et al so as to completely enclose the blood sample therein so that the outside environment is not contaminated by the blood sample. It also would have been obvious to one of ordinary skill in the art to change the shape of the agitator vane leaflets taught by Nippoldt et al to the various different shapes recited in claims 22-40 since shape is a result effective parameter that can be experimentally altered to optimize mixing of a blood sample and reagents in the test chamber, and the change in shape of an object with no unexpected results is an obvious design choice. See *In re Dailey et al*, 149 USPQ 47.

10. Claims 3-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims since none of the prior art of record teaches or fairly suggests a system for performing a coagulation time test on a biological sample comprising a test cartridge formed of a cartridge housing having at least one closed test chamber therein into which a test sample is deposited, an agitator mounted at a pivot point in the test chamber, wherein the agitator has an agitator vane having the specific configurations as recited in claims 3-20 located entirely within the test chamber as the agitator rotates, and a test instrument having an instrument housing including a cartridge receptacle for supporting the test cartridge, a sweeping means for sweeping the agitator vane about the pivot point through the test sample in the test chamber, a detecting means for detecting the reduction of sweeping movement of the agitator vane, and a timing

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means for timing a coagulation test time elapsed from the commencement of sweeping of the agitator vane until detection of reduction of the sweeping movement. In particular, none of the prior art of record teaches or fairly suggests an agitator vane located in a closed test chamber used for determining the coagulation time of a blood sample, wherein the agitator vane is located entirely within the test chamber as the vane is rotated and swept through the blood sample, and a timing means for timing a coagulation test time elapsed from the commencement of sweeping of the agitator vane until detection of reduction of the sweeping movement.

11. Applicant's arguments filed August 6, 2007 have been fully considered but they are not persuasive.

The objection to the disclosure originally made in the last Office action mailed on April 2, 2007 has been maintained for the reasons cited above in the first paragraph of this Office action. The previous rejection of the claims on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims in application serial no. 10/892,000 has been maintained since both this application and application serial no. 10/892,000 have the same effective filing date, the instant claims have not been amended to patentably distinguish over the claims in application serial no. 10/892,000, and Applicants have not filed an appropriate terminal disclaimer over application serial no. 10/892,000.

Applicants argue the rejections of the claims under 35 USC 102(e) and 35 USC 103 as being anticipated by or obvious in view of Nippoldt et al (US 2005/0255601) by stating that this reference is not prior art against the instant claims since the instant application is a CIP of application serial no. 11/047,026, which corresponds to the Nippoldt et al publication. This argument is not found persuasive since priority to application serial no. 11/047,026 is not proper

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for the reasons given in the petition decision dated September 21, 2007. Therefore, both the rejections of the claims under 35 USC 102(e) and 35 USC 103 as being anticipated by or obvious in view of Nippoldt et al have been maintained.

The previous grounds of rejection of the claims under 35 USC 103 as being obvious over the combinations of Mpock et al in view of Bote Bote and Chow, and Mpock et al in view of Bote Bote and Chow, and further in view of Nippoldt et al, have been withdrawn in view of Applicants' persuasive arguments. Therefore, the Examiner will not address Applicants' arguments.

Applicants are requested to file a terminal disclaimer over application serial no. 10/892,000.

12. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

October 29, 2007

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP 1000 1700